

REMARKS

This Amendment is submitted in reply to the non-final Office Action dated August 7, 2008. There are no fees due with this Amendment. The Commissioner is hereby authorized to charge any other fees that may be required or credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 115808-504 on the account statement.

Claims 1 and 3-14 are pending. Claim 2 was previously canceled. Claims 1, 3 and 11 are objected to. Claims 4 and 10 are rejected under 35 U.S.C. § 112. Claim 10 is rejected under 35 U.S.C. § 101. Claims 1, 4-7, 9 and 11 are rejected under 35 U.S.C. §102. Claims 1 and 3-14 are rejected under 35 U.S.C. §103. In response, Claims 1, 8-11 and 13-14 have been amended and Claim 4 has been canceled. In view of the amendments and for the reasons set forth below, Applicants respectfully request that the rejection be withdrawn.

In the Office Action, Claims 1, 3 and 11 are objected to for “cm3.” The Patent Office alleges that the “3” is expected to be the exponent of “cm.” See, Office Action, page 2, lines 10-11. In response, Applicants have formatted the “3” to be a superscript. As such, the “3” is now the exponent of the “cm.”

Accordingly, Applicants respectfully request that the objection of Claims 1, 3 and 11 be reconsidered and withdrawn.

In the Office Action, Claim 10 is rejected under 35 U.S.C. §112, second paragraph as being indefinite. Specifically, the Patent Office alleges that “Claim 10 provides for the use of the pellets as a delivery system, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass.” See, Office Action, page 2, lines 16-18. Claim 10 is also rejected under 35 U.S.C. §101 because the Patent Office alleges that “the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process.” See, Office Action, page 3, lines 1-3. In response, Claim 10 has been amended to recite the delivery system of claim 9, wherein the delivery system comprises a food product selected from the group consisting of moist, semi-moist, semi-dry, and combinations thereof. The amendment does not add new matter. The amendment is supported in the specification at, for example, page 3, lines 31-33. As amended, Applicants respectfully submit that Claim 10 no longer recites a “use” claim and now

properly dependents from Claim 9. For at least these reasons, Applicants submit that Claim 10 fully complies with the requirements of 35 U.S.C. §112, second paragraph and 35 U.S.C. §101.

Accordingly, Applicants respectfully request that the rejections of Claim 10 under 35 U.S.C. §112, second paragraph and 35 U.S.C. §101 be reconsidered and withdrawn.

In the Office Action, Claim 4 is also rejected under 35 U.S.C. §112, second paragraph as being indefinite. Specifically, the Patent Office alleges that “It is unclear what is meant by ‘105 to 1014 viable micro-15 organisms.’” See, Office Action, page 3, lines 13-15. In response, Claim 4 has been canceled.

Accordingly, Applicants respectfully request that the rejection of Claim 4 under 35 U.S.C. §112, second paragraph is now rendered moot.

In the Office Action, Claims 1, 4-7, 9 and 11 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,480,641 to Casas-Perez (“*Casas-Perez*”). Currently amended independent Claim 1 recites, in relevant part, a pellet comprising a compacted inner matrix and at least one coating, wherein the inner matrix comprises particles comprising at least one inert carbohydrate and 10^5 to 10^8 viable micro-organisms per gram of pellet. Currently amended independent Claim 11 recites, in relevant part, a process for obtaining pellets, which comprises mixing a first preparation of micro-organisms and inert carbohydrates, drying the first preparation to form particles, mixing the particles and further components to form a second preparation, drying the second preparation to an Aw below 0.3, and compacting the second preparation under pressure to obtain pellets comprising a volume of at least 0.02 cm^3 . The amendments do not add new matter. The amendments are supported in the specification at, for example, page 11, line 8-page 12, line 2.

In accordance with the present disclosure, although the micro-organisms may be provided in dried form, the micro-organisms need not necessarily be present in a dried form from the beginning of the manufacturing process. Instead, the micro-organisms may be mixed directly after fermentation with further components of the inner matrix and dried to form particles. For example, such particles may be obtained by mixing micro-organisms with inert carbohydrates after fermentation and spray drying or fluidized-bed drying the mixture. See, specification, page 11, line 8-page 12, line 2.

The particles comprising micro-organisms and inert carbohydrates provide the advantages that the micro-organisms are less susceptible to subsequent compaction and, thus, the micro-organisms will survive for extended periods of time. For example, the specification clearly demonstrates that the best recovery after storage time of about 30-60 days was obtained when the bacterial strains were present in particulate form. The use of fragile bacterial cultures, for instance, freeze-dried preparations without added carbohydrates, is less recommended when applied in kibbles compacted at high compaction pressures as high losses in viability were observed. Granular preparations, for example containing significant amounts of carbohydrates in a spray dried bacterial preparation, worked very well. See, specification, page 11, line 8-page 12, line 2; page 25, lines 8-14. Applicants respectfully submit that *Casas-Perez* fails to disclose or suggest every element of the present claims.

Casas-Perez fails to disclose or suggest a pellet comprising an inner matrix comprising particles comprising at least one inert carbohydrate and 10^5 to 10^8 viable micro-organisms per gram of pellet as required, in part, by Claim 1. *Casas-Perez* also fails to disclose or suggest a process for obtaining pellets comprising mixing a first preparation of micro-organisms and inert carbohydrates, drying the first preparation to form particles, mixing the particles and further components to form a second preparation, drying the second preparation to an Aw below 0.3, and compacting the second preparation under pressure to obtain pellets comprising a volume of at least 0.02 cm^3 as required, in part, by Claim 11. As discussed above, the “particles” of the present invention are formed by mixing the micro-organisms after fermentation with inert carbohydrates and the drying the subsequent mixture. Upon drying, the micro-organisms are embedded in the inert carbohydrates in particulate form, which aids in extending the life of the micro-organisms.

Casas-Perez is entirely directed toward either coating whey pellets with lyophilized *L. reuteri* cells suspended in oil, or mixing the suspended *L. reuteri* cells in oil with whey powder and compressing the mixture. See, *Casas-Perez*, col. 3, line 55-col. 4, line 57. Accordingly, because *Casas-Perez* discloses *L. reuteri* cells suspended in oil, *Casas-Perez* cannot disclose particles comprising at least one inert carbohydrate and 10^5 to 10^8 viable micro-organisms per gram of pellet as required, in part, by Claim 1. Further, *Casas-Perez* also discloses suspending “lyophilized” *L. reuteri* cells in oil, which means that the micro-organisms of *Casas-Perez* are

dried before the micro-organisms even contact any oil. As such, *Casas-Perez* cannot disclose or suggest a process for obtaining pellets comprising mixing a first preparation of micro-organisms and inert carbohydrates, drying the first preparation to form particles, mixing the particles and further components to form a second preparation, drying the second preparation to an Aw below 0.3, and compacting the second preparation under pressure to obtain pellets comprising a volume of at least 0.02 cm³ as required, in part, by Claim 11. For at least these reasons, Applicants respectfully submit that *Casas-Perez* fails to disclose each and every element of the present claims.

Accordingly, Applicants respectfully request that the anticipation rejection in view of *Casas-Perez* be reconsidered and withdrawn.

In the Office Action, Claims 1 and 3-14 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,888,171 to Okonogi et al. ("*Okonogi*") in view of EP 0298605 to Klapwijk et al. ("*Klapwijk*") and WO 99/48372 to Van Lengerich ("*Van Lengerich*"). As discussed above, the presently amended claims are directed, in part, to pellets having particles formed from micro-organisms and inert carbohydrates. The particles comprising the micro-organisms and inert carbohydrates provide the advantages that the micro-organisms are less susceptible to subsequent compaction and, thus, the micro-organisms experience better survival rates. Applicants respectfully submit that, even if combinable, the cited references fail to disclose or suggest every element of the present claims.

Okonogi, *Klapwijk* and *Van Lengerich* fail to disclose or suggest a pellet comprising an inner matrix comprising particles comprising at least one inert carbohydrate and 10⁵ to 10⁸ viable micro-organisms per gram of pellet as required, in part, by Claim 1. *Okonogi*, *Klapwijk* and *Van Lengerich* also fail to disclose or suggest a process for obtaining pellets comprising mixing a first preparation of micro-organisms and inert carbohydrates, drying the first preparation to form particles, mixing the particles and further components to form a second preparation, drying the second preparation to an Aw below 0.3, and compacting the second preparation under pressure to obtain pellets comprising a volume of at least 0.02 cm³ as required, in part, by Claim 11.

Instead, *Okonogi* teaches granular products having a core material and an adherent material containing dried viable microorganism. The cultivated bacteria of *Okonogi* are subjected to freeze-drying or vacuum drying according to a usual method prior to contacting the

adhesive material. As such, the granular product of *Okonogi* cannot disclose the inner matrix comprising the claimed particles or methods of preparing the claimed particles. See, *Okonogi*, col. 3, line 66-col. 4, line 4. Applicants also submit that secondary references *Klapwijk* and *Van Lengerich* fail to remedy the above deficiencies in *Okonogi*.

For example, *Klapwijk* and *Van Lengerich* fail to disclose or even suggest pellets having a core layer and an inner matrix having microorganisms, let alone the inner matrix of Claim 1, which comprises particles comprising at least one inert carbohydrate and 10^5 to 10^8 viable micro-organisms per gram of pellet. Further, *Klapwijk* and *Van Lengerich* fail to disclose or suggest any methods for producing pellets having a core layer and an inner matrix having microorganisms, let alone the process of Claim 11, wherein the inert carbohydrates and the micro-organisms are dried at the same time after being mixed after fermentation. Instead, *Klapwijk* is entirely directed toward aqueous suspensions of viable microflora that have improved ambient stability and is usable in fermentation. See, *Klapwijk*, Abstract. *Van Lengerich* is entirely directed toward products having encapsulated organisms. See, *Van Lengerich*, Abstract. As such, Applicants respectfully submit that *Okonogi*, *Klapwijk* and *Van Lengerich* fail to disclose or suggest each and every element of the present claims.

Applicants also respectfully submit that the cited references are not properly combinable because the references are directed to completely different inventions. On one hand, *Okonogi* and *Van Lengerich* are directed to pelletized compositions. See, *Okonogi*, col. 3, lines 9-23 and *Van Lengerich*, page 32, lines 11-13. By contrast, *Klapwijk* is not directed to pelletized compositions.

Klapwijk is directed to preparing bacterial compositions used in breadmaking. See, *Klapwijk*, page 1, lines 1-3. The examples disclosed in *Klapwijk* clearly only teach processes for preparing cell concentrate mixtures or processes for incorporating these mixtures into bread dough including sough dough and rye flour mixtures. See, *Klapwijk*, Examples 1-7. The Patent Office asserts that *Klapwijk* is not limited to breadmaking, however, and that *Klapwijk* has application in food, animal feed and agricultural industries. See, Office Action, page 10, lines 1-2. However, Applicants respectfully disagree and assert that the portion of the disclosure which the Patent Office cites for this proposition (page 2, lines 3-4) states, instead, that “fermentation” may play a role in different food industries, not the cell concentrates of *Klapwijk*. Further, the

title of *Klapwijk* even recites “Stable bacterial composition and process for breadmaking using this composition.” See, *Klapwijk*, Title (emphasis added). Moreover, the Advisory Action even admits that *Klapwijk* does not teach a compaction process or compositions capable of being compacted into pellets. See, Advisory Action, page 3.

Applicants recognize that a need exists for a delivery system for probiotics, which provides a still prolonged life span of the probiotics in a liquid, moist or semi-moist environment. In particular, Applicants recognize the need to provide stable probiotics or a probiotics delivery system that can be added to a food product having an Aw (water activity) value above optimal for probiotics to survive. See, specification, page 3, lines 1-10. Applicants surprisingly found that by compacting dried micro-organisms together with a matrix, which may consist of dried food material, and by coating the pellets with a food-grade moisture barrier, Applicants could obtain an excellent stability over storage time. See, specification, page 3, lines 14-17. Since incorporating probiotics into pellets, therefore, provides clear advantages over other product forms, one would have no reason to combine *Okonogi* and *Van Lengerich* (palletized compositions) with *Klapwijk* (non-pellet compositions) to arrive at the present claims.

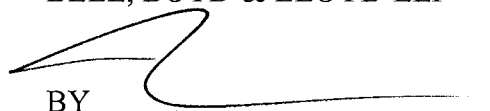
Therefore, Applicants respectfully submit that the combination of cited art fails to disclose or suggest every element of the present claims. Moreover, Applicants submit that the cited references are not properly combinable.

Accordingly, Applicants respectfully request that the obviousness rejection in view of *Okonogi*, *Klapwijk* and *Van Lengerich* be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims that could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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